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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/040,803 | DARROW ET AL. | |
| | Examiner | Art Unit | |
| | William W. Moore | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to The amendment filed 6 July 2004 and the interview conducted 11 August 2004.
2. ☒ The allowed claim(s) is/are 15,16,28 and 29.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>20040811</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

15. (Amended) A method of identifying compounds that inhibit serine protease C-E activity, comprising:

(a) conducting a test assay wherein combining a test compound, a serine protease C-E comprising a catalytic domain amino acid sequence as set forth in SEQ ID NO:8, and a labeled substrate are combined and the rate of reaction is measured; and

(b) conducting a control assay wherein a serine protease C-E comprising a catalytic domain amino acid sequence as set forth in SEQ ID NO:8 and a labeled substrate are combined and the rate of reaction is measured; and,

(c) comparing measuring a change in the rates of the reaction of with the labeled substrate in steps (a) and (b) to detect a decrease of rate of reaction in step (a) relative to step (b) which indicates that inhibition of serine protease C-E activity by the test compound for comparison with a control assay measurement with the is an inhibitor of said serine protease C-E and the labeled substrate but without the test compound;

whereby an inhibitory compound is identified.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Linda S. Evans on August 11, 2004.

The following is an examiner's statement of reasons for allowance:

Applicant's arguments in the Response filed July 6, 2004, addressing the rejection of record of claims 15, 16, and 28 herein under 35 U.S.C. § 103(a) are persuasive in establishing that, because the prior art does not suggest the amino-terminal amino acid sequence alteration of that domain in set forth in SEQ ID NO:8, it would not have been obvious to one of ordinary skill in the art at the time the invention was made to conduct

a screening assay to detect inhibitors of serine protease C-E activity with a protease comprising the protease domain present in SEQ ID NO:8 herein. The above examiner's amendment clarifies procedures that Applicant had combined in a single clause (b) in amending claim 15 in the response filed July 6, 2004, by separating them into two steps and adding the details that one of ordinary skill in the art at the time the invention was made would be aware to be part of such an assay process. The specification need not teach that which is well known in the art and the above claim amendment restates Applicant's intended procedure in claim 15 in order to more consistently describe an assay to identify inhibitors. The claim is further amended above to introduce a terminal clause that completes the statement of purpose in the claim preamble.

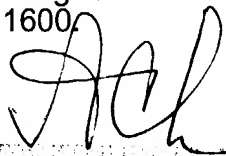
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
August 11, 2004



WILLIAM W. MOORE
EXAMINER
TECHNICAL STAFF